

# TARVA Newsletter

RANDOMISED CLINICAL TRIAL

TARVA is a clinical trial for patients with ankle arthritis who are considering surgery



TARVA stands for Total Ankle Replacement Versus Arthrodesis (fusion), which are the two main surgical treatments for ankle arthritis.

Surgery type is allocated in a fair and even way like the toss of a coin. For one year following surgery, the success of each operation will be assessed and compared in terms of each patient's ankle function and quality of life.



## News

### 212 Patients Recruited

Additionally, 180 patients have been randomised and 151 have had their surgery as part of the trial (as of end of August 2017). **As we are now more than half-**



**way towards our recruitment goal, our thanks to all the patients who have participated in TARVA so far!**

### 68 patients completed trial

68 patients have attended their 1-year follow-up visit (to end of August 2017) and have therefore completed the initial part of the TARVA trial.

### Long-term follow up

Our first TARVA patient reached their 2-year surgery anniversary date in April, and has been sent our long-term follow up questionnaire about their progress. The 2, 5 and 10 year follow-up questionnaires will be key for more fully understanding the impact of having TAR and arthrodesis operations.

### Qualitative research project into recruitment

A qualitative sub-study investigating barriers to recruitment (conducted by Prof Damian Griffin at Warwick University) is being conducted at five of our sites. Please see page 4 for further details on how this will help patients and the NHS.

### Welcome to our new Data Manager

Since the last newsletter, Miriam Pollard has joined the TARVA team in the role of Data Manager. We wish her predecessor, Rosie Hamilton, all the best in her new role.

## Social Media



Follow us on Twitter [@TARVA\\_Trial](#)



Search for [TARVA clinical trial](#) on Facebook



[www.anklearthritis.co.uk](http://www.anklearthritis.co.uk)

## Funding

TARVA is funded by the National Institute for Health Research Health Technology Assessment (project number 12/35/27).



**Miss Miriam Pollard**  
TARVA Data Manager, CCTU, UCL

## Meet the Data Manager

### Q What does being a Data Manager involve?

**A** I am responsible for tracking the progress of the trial, quality checking the data collected and assisting sites with any data-related questions.

### Q Why is your role important?

**A** It is important that I ensure that the data is completed and of a high quality so that the trial results can be confidently reported. Checking the data also enables me to make sure the trial is completed according to the protocol.

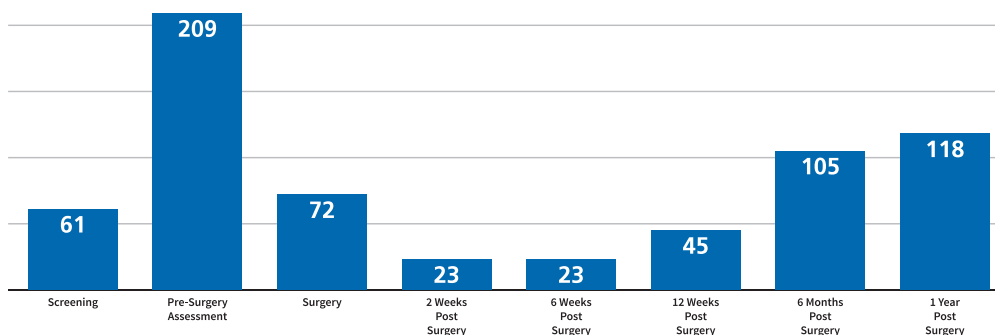
### Q What do you enjoy the most about your role?

**A** Day-to-day I liaise with a wide range of people who are involved in the TARVA trial in different ways, from both the CCTU and all the site teams.

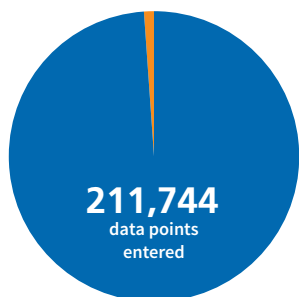
## Data Entry Update

The TARVA trial collects a minimum of **656** data items per patient.

This chart shows how these data items are spread across each study visit.

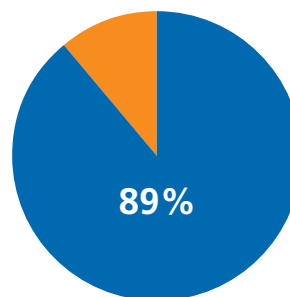


The chart below shows the number of data items entered to date, with only 1% of data items currently missing.



■ Number of data items entered    ■ Missing data items

89% of CRFs (trial reporting forms) have been entered in a timely manner after the patient has attended the visit.

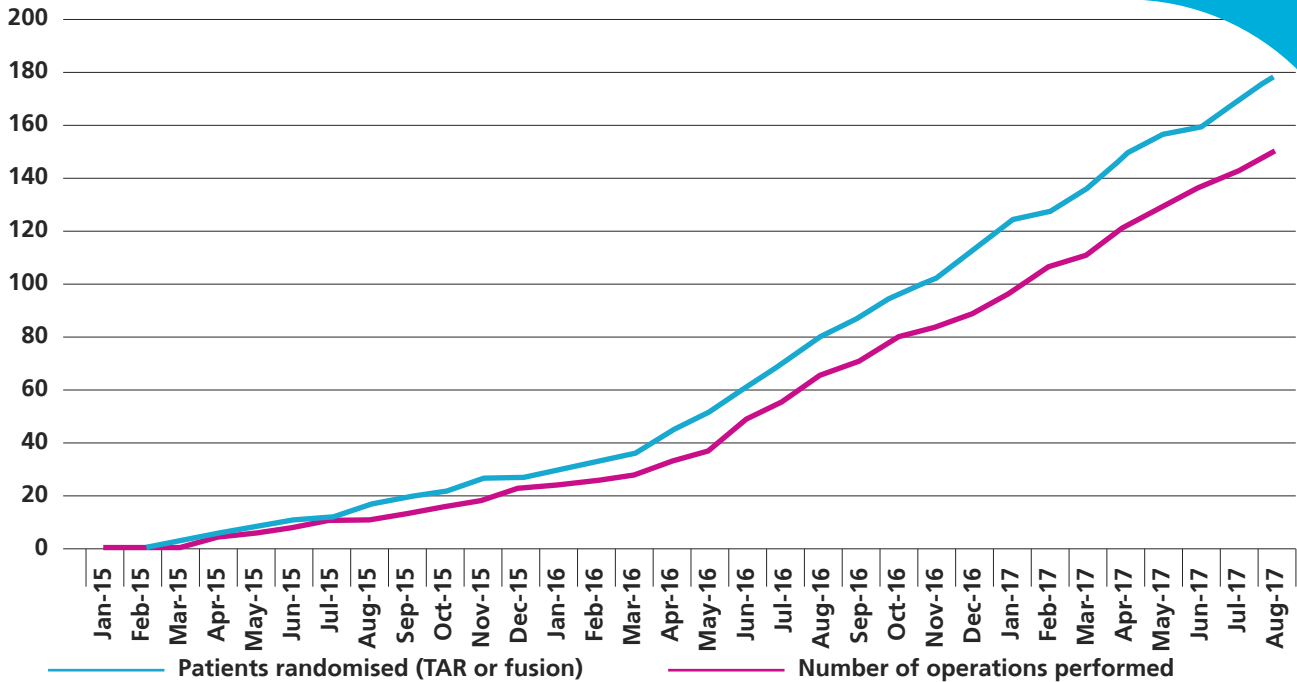


■ CRFs entered within 30 days    ■ CRFs not entered within 30 days

## Recruitment Update

At the end of August 2017, 212 patients have been recruited to TARVA, 180 randomised, and 151 have received their operation. We are over half way to reaching our goal of 328 patients!

This graph shows how the number of patients joining the trial has continued to steadily increase in recent months.



## Health Economics in the TARVA trial

We will conduct a health economic analysis to compare how much it costs to provide ankle fusion and ankle replacement procedures for both the patient and the NHS.

Patients are asked about their use of social services and the expense of living with their arthritis condition, such as home care or special equipment.

The effects of the procedures on patients' quality of life will also be analysed. This is measured using the EQ-5D questionnaire, which is used across many clinical areas.

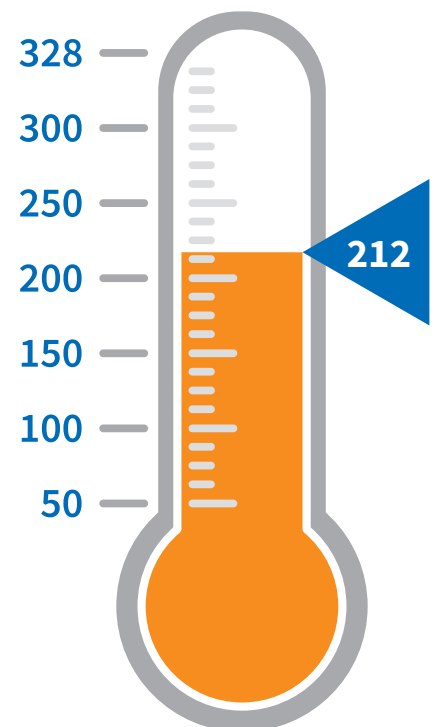
A comparison of these questionnaires at various points for each patient will allow us to better understand the health economic impact of TAR and Arthrodesis treatments, and in turn help the NHS best allocate resources to optimise treatments for its patients.

Our aim is to also consider the long-term differences between the procedures - this is because the impact of ankle surgery can be experienced many years after surgery.



Mr Torsten Chandler Health Economist, CCTU, UCL

## TARVA recruitment to date - goal 328 patients





## Qualitative research project



**Dr Alba Realpe**  
Research Fellow, Warwick University

**Dr Alba Realpe explains:**

“Our team at Warwick University will record a small number of consultations with patients to better understand how research staff explain their medical condition, treatments and possible participation in the TARVA trial .”

We will also be conducting interviews with the lead consultants and research coordinators and nurses at the Derby, Newcastle, Oswestry, Stanmore and Wrightington sites.

By analysing these interviews we can use the findings to help improve the number of patients entering the study and share best practises. ”

## Typical Participant timeline

### Consultation

#### 3 months before surgery:

Consent to join TARVA  
MRI scan of affected ankle

#### 1 month before surgery:

Pre-operation assessment for routine checks and health related questionnaires

#### After successful assessment:

Randomised to receive either total ankle replacement or fusion operation

#### Day 0:

TARVA operation

#### 5 after-surgery visits to check progress and complete study questionnaires:

- 2 weeks after surgery
- 6 weeks after surgery
- 12 weeks after surgery
- 6 months after surgery
- 1 year after surgery

## Celebrities in the Spotlight



**Tom Cruise** broke his ankle while performing a stunt on the set of “Mission: Impossible 6”, halting filming while he recovers.

Olympic champion **Greg Rutherford** was unable to compete in the World Athletics Championships in London due to an injury to the ligaments in his ankle.



### Editorial team contact details

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**If you have a story or case study you would like included in a future newsletter, please let us know at [tarvanewsletter@rnh.nhs.uk](mailto:tarvanewsletter@rnh.nhs.uk)**

### Coming in the next newsletter:

- 1) Recruitment update
- 2) Trial progress and completion timelines
- 3) Meet a nursing team
- 4) Update from annual Investigators meeting